

## **REMARKS**

Claims 99-103 are pending in the present application. Claims 101 and 102 were withdrawn from consideration. By way of the foregoing amendment, claim 99 has been amended and claims 100-103 have been canceled without prejudice to or disclaimer of the subject matter contained therein. Support for the foregoing amendment can be found throughout the specification and claims as filed. No new matter enters by way of the foregoing amendment.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

### ***I. Claim Objections***

Claim 100 remains objected to in the Office Action for reciting non-elected subject matter. Applicants note that claim 100 has been canceled without prejudice to or disclaimer of the underlying subject matter, and therefore the objection to claim 100 is moot. As such, Applicants respectfully request that the objection be withdrawn.

### ***II. Claim Rejections – 35 U.S.C. § 103***

Claims 99, 100, and 103 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Skurkovich et al. (U.S. Patent No. 5,888,511). Applicants note that claims 100 and 103 have been canceled without prejudice to or disclaimer of the underlying subject matter, and as such, the response is directed to the rejection as it relates to claim 99. The rejection of claim 99 is traversed for the reasons that follow.

Independent claim 99, as amended, is directed to a method for treating an autoimmune disease in a subject, consisting of administering to the subject a therapeutically effective amount of a composition consisting of one or more humanized, monoclonal anti-IFN- $\alpha$  antibodies or antigen-binding fragments thereof and a diluent, a preservative, a solubilizer, an emulsifier, an adjuvant, a carrier, a buffer, a pharmaceutical additive, a detergent, an anti-oxidant, a bulking substance, a tonicity modifier, a flavoring agent, a lubricant, a suspending agent, a filler, a glidant, a compression aid, a binder, a tablet-disintegrating agent, an encapsulating material, a sweetener, a thickening agent, a color, a viscosity regulator, a stabilizer, an osmo-regulator, a pharmaceutically acceptable propellant,

a flavorant, a dye, a coating, or a combination of any thereof, where the autoimmune disease is psoriasis.

Applicants assert that there is no motivation to modify the Skurkovich et al. reference, nor is any reasoning provided as to why a skilled artisan would modify the reference, to arrive at methods for the treatment of psoriasis as currently claimed. *See, MPEP § 2142.*

Skurkovich et al. does not disclose effective treatment methods for psoriasis comprising the administration of a composition consisting of humanized, monoclonal antibodies (or antigen-binding fragments thereof) against IFN- $\alpha$  alone (i.e., as the sole active ingredient). Skurkovich et al. only discloses alleged treatments comprising administration of antibodies against a single cytokine (such as IFN- $\alpha$ ) as the sole active ingredient of a composition that is administered in the context of rheumatoid arthritis and AIDS (see, e.g., *Column 3, line 57-column 4, line 9 of Skurkovich et al.*) In fact, Skurkovich et al. teaches that multiple therapeutic agents may be required to effectively treat autoimmune diseases:

... because autoimmune diseases are complex, often characterized by multiple cytokine abnormalities, effective treatment appears to require the simultaneous administration or utilization of several agents, each targeting a specific cytokine pathway or its by-product. To meet this need, the methods of treatment of the present invention include not only the use of specific antibodies,. [sic] but also provide pleiotrophic autoimmune inhibitors, including antibodies to cytokines and HLA class II antigens, and antigens for the removal of autoantibodies to target cells or DNA. The use of these antibodies and antigens as disclosed in the present invention results in the removal, neutralization or inhibition of the pathogenic cytokine(s), HLA class II antigens, and/or autoantibody(ies) to target cells or DNA from the autoimmune patient, thereby significantly improving the quality of life of the individual.

*Column 4, lines 9-24 (emphasis added).*

Thus, there is simply no suggestion or motivation in Skurkovich et al. related to the use of humanized, monoclonal anti-IFN- $\alpha$  antibodies or antigen binding fragments thereof as the sole active ingredient for the treatment of psoriasis. In addition, no suggestion or motivation has been presented as to why one skilled in the art would modify Skurkovich to arrive at a psoriasis treatment method using humanized, monoclonal anti-IFN- $\alpha$  antibodies or antigen binding fragments thereof as the sole active ingredient as set forth in claim 99.

Accordingly, because there is no rationale supporting a conclusion of obviousness, Applicants respectfully request that this rejection be withdrawn.

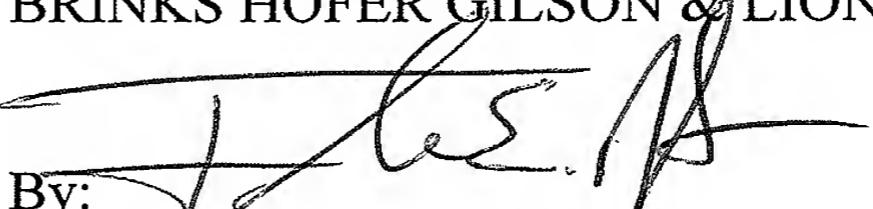
For the foregoing reasons, claim 99 is considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

**The Director is hereby authorized to charge any appropriate fees that may be required by this paper, and to credit any overpayment, to Deposit Account No. 23-1925.**

Respectfully submitted,

BRINKS HOFER GILSON & LIONE

By:

  
Thomas E. Holsten  
Registration No. 46,098

Date: May 6, 2009

2801 Slater Road, Suite 120  
Morrisville, NC 27560  
919.481.1111  
681696v1